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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,382	04/20/2001	Harry D. Danforth	0100.00	9258
25295	7590	11/24/2004	EXAMINER	
USDA, ARS, OTT 5601 SUNNYSIDE AVE RM 4-1159 BELTSVILLE, MD 20705-5131			HINES, JANA A	
		ART UNIT	PAPER NUMBER	
		1645		

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/838,382	DANFORTH ET AL.
Examiner	Art Unit	
Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 September 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3-16 is/are pending in the application.
- 4a) Of the above claim(s) 3-13 is/are withdrawn from consideration.
- 5) Claim(s) 14 and 15 is/are allowed.
- 6) Claim(s) 16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed September 7, 2004 has been entered. Claims 1-2 have been cancelled. Claims 3-13 have been withdrawn. Claims 14-16 are under consideration in this office action.
2. A complete reply to the final rejection must include cancellation of nonelected and withdrawn claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Therefore, applicants must cancel claims 3-13.

Response to Arguments

3. Applicant's arguments filed September 7, 2004 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The written description rejection of claim 16 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons already of record. The rejection was on the grounds that the written description in this case fails to set forth a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15.

Applicants' assert that given the guidance of the specification and claims, one of skill in the art would know whether these characteristics correspond to *E. maxima*-I. However, this is a written description rejection and the issue is that neither the specification nor the claims teach the identity of a variant strain that is not ATCC-PTA 4959 yet corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959). The issue is not about whether one skilled in the art would know how to analysis the claimed characteristics of a variant strain of *E. maxima* to determine its correspondence to *E. maxima*-I. The function of the description requirement is to ensure that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her; how the specifica-tion accomplishes this is not material. *In re Herschler*, 591 F.2d 693, 700-01, 200 USPQ 711, 717 (CCPA 1979) and further reiterated in *In re Kaslow*, 707 F.2d 1366, 707 F.2d 1366, 217 USPQ 1089 (Fed. Cir.1983). Applicants have failed to show that they were in possession of the variant strain claimed in claim 16.

Applicants' urge that no undue experimentation would be required and that the unidentified variant strain could also be used in a vaccine, therefore the rejection should be withdrawn. However, undue experimentation is not the issue. Applicants' have not shown that they were in possession of a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959). The satisfaction of the enablement requirement does not satisfy the written description requirement. See *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make

and use the invention, but still fail to comply with the written description requirement). See also *In re DiLeone*, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). The instant specification and claims describe a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) by its function i.e., immunization and cross-reactivity abilities, however this description does not describe the claimed variant strain itself, nor does it provide the identity of the strain.

Applicants' assert that the cell line has been described by identifying characteristics and such identification is sufficient to satisfy the written description requirements. However, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Applicants' have not even pointed to support for the variant strain of claim 16; rather applicants' have disclosed some characteristics of the unidentified strain. There is evidence that other variant strains known in the art do not have the required characteristics. There is no teaching in the specification that discloses the

identity of a variant strain that has the claimed characteristics to thereby indicate that said variant strain has no detectable immunological cross reactivity with *E.maxima*-GLP. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991). It is noted that functional limitations alone are not sufficient to satisfy the written description requirement.

A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process as is the case here. Applicants' specification continuously point out strains that do not meet the claimed limitations, with the exception of the deposited strain. Thus one of skill in the art could not immediately envision the claimed variant strain. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) ("If n-

propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.") (emphasis in original); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("the specification does not clearly disclose to the skilled artisan that the inventors ... considered the ratio... to be part of their invention There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion". Similarly, it appears that the instant case sets forth an undisclosed variant strain and asserts that this undisclosed strain has some functional limitations. However, there is no actual disclosure of the claimed variant strain. Moreover, the functional limitations do not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species.

Therefore the rejection is maintained because applicants' arguments are not persuasive and because applicants' have failed to provide support that they were in possession of this variant strain as claimed.

5. The new matter rejection of claim 16 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.

Applicants assert that support for claim 16 is found in original claim 2. However, an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). The issue of a lack of adequate written description and new matter may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. For example, consider the claim "A gene comprising SEQ ID NO:1." A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (e.g., promoters, enhancers, coding regions, and other regulatory elements) which are also included. The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-

recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. *In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993). Thus in the instant case, original claim 2 drawn to " an immunovariant strain of *Eimeria maxima* that corresponds in characteristics to the strain *E. maxima*-I" is not commensurate to claim 16. Claim 2 fails to describe a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15. Thus, claim 16 incorporates new matter and applicants' arguments are not persuasive.

Neither the specification nor originally presented claims provides support for a variant strain of *Eimeria maxima* wherein said variant corresponds in characteristics to the strain *E. maxima*-I (ATCC number PTA-4959) as set forth in claim 15 wherein: immunization with said variant strain or *E. maxima* -I (ATCCC number PTA-4959) protects against challenge with said variant strain or *E. maxima*-I (ATCC number PTA-4959), but does not protect against challenge with *E. maxima*-GLP, an indication that said variant strain has no detectable immunological cross reactivity with *E. maxima*-GLP.

It is noted that the examples and original claims fail to disclose the identity of a variant strain that is not the deposited strain ATCC PTA-4959 having the claimed characteristics. Therefore, it appears that there is no support in the specification or

original claims. Therefore, claim 16 incorporates new matter and the rejection is maintained.

Allowable Subject Matter

6. Claims 14-15 are allowed.

Conclusion

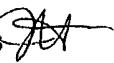
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
November 16, 2004

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER